IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF NORTH CAROLINA
CHARLOTTE DIVISION
CIVIL ACTION NO. 3:22-MD-03036-KDB

IN RE: GARDASIL PRODUCTS LIABILITY LITIGATION	)	**MDL No. 3036**
	)	**THIS DOCUMENT RELATES TO ALL CASES**

ORDER

THIS MATTER is before the Court on Plaintiffs' "Motion to Limit Application of the Court's Order on Defendant's Motion for Partial Judgment on the Pleadings to Plaintiffs Bergin and America" and "Motion to Find that Subjecting Gardasil Personal Injury Claims to the Vaccine Act Violates the Presentment Clause of the United States Constitution." (Doc. No. 136). While the first motion is nominally related to the application of the Court's previous Order, (Doc. No. 132), the substance of these motions is more accurately reflected by the Plaintiffs' second motion, both of which are asserted in the same document. Although the broad constitutional question now raised by Plaintiffs is not the type of argument that the Court intended to invite in allowing other plaintiffs to raise *individual* issues after the resolution of Plaintiffs Bergin and America's bellwether motions, the Court will consider the merits of Plaintiffs' constitutional challenge so as to put it to rest for all Plaintiffs. For the reasons discussed below, the Court concludes that there is no constitutional violation of the "Presentment Clause" in applying the National Childhood Vaccine

Injury Act ("Vaccine Act" or "Act"), 42 U.S.C. § 300aa-1 *et seq.*, to Plaintiffs' personal injury claims related to the Gardasil vaccine.

I. FACTS AND PROCEDURAL HISTORY

Since August 2022, this Court has been the forum for a multi-district litigation ("MDL") in which nearly two hundred cases asserting vaccine injury claims against Merck have been consolidated. (Doc. No. 2). Each Plaintiff alleges that he or she has suffered harm caused by vaccination with Gardasil, a Human Papillomavirus ("HPV") vaccine which seeks to prevent cervical and other cancers believed to be associated with HPV.

Prior to the creation of the MDL, several motions to dismiss pursuant to Federal Rule of Civil Procedure 12 were either decided or pending in cases which then became consolidated in the MDL. All pending motions were stayed by this Court's First Pretrial Order. However, the Court permitted Merck to file proposed "bellwether" Rule 12 motions in two cases, *Bergin v. Merck & Co., Inc. et al.*, No. 3:22-CV-00117, and *America v. Merck & Co., Inc. et al.*, No. 3:22-CV-00585. (*See* Doc. Nos. 35 at pp. 2-4; Doc. No. 58 at 7). In February 2023, Merck filed a Motion for Partial Judgment on the Pleadings in *Bergin* and *America* (Doc. No. 68) seeking dismissal of Plaintiffs' alleged "design defect" and "direct warning" claims based on the argument they are preempted by the National Childhood Vaccine Injury Act, 42 U.S.C. § 300aa-1, *et seq*. (the "Vaccine Act") and their "manufacturing defect" and fraud claims for allegedly inadequate pleading.

After full briefing and oral argument, the Court ruled on the motion on March 20, 2024, in part granting and in part denying the motion. (Doc. No. 132). Consistent with the "bellwether" nature of the motion, the Court applied the ruling to "all substantially similar allegations/claims asserted in the cases subject to the MDL." (*Id*. at 26). However, the Court allowed "Parties who

believe they have good cause (as discussed in the Order) to avoid the application of [the] ruling" to file a motion seeking relief from the Order. On April 19, 2024, all the then-remaining Plaintiffs (other than Bergin and America) filed the present motions, arguing that they should not be bound by the Court's March 20 Order to the extent it relates to the Vaccine Act because, as a matter of constitutional law, the Vaccine Act does not apply to Gardasil, which was not included in the Act's original table of covered vaccines. (*See* Doc. 136 at 9). Plaintiffs' motions rest only on their constitutional claim (which was not asserted in the bellwether motions), and none argue that they have made allegations that are materially different from Plaintiffs Bergin or America. (*See* Doc. No. 132 at 9, fn. 9).

The Court later granted the Parties' joint motion to extend the time for briefing the motions, and briefing concluded on June 5, 2024. No party requested that the Court hold oral argument (and the Court does not believe that oral argument would assist it in deciding these motions). Therefore, the motions are ripe for the Court's ruling.

II. DISCUSSION

Plaintiffs' constitutional challenge to the Vaccine Act rests on their argument that "the Act's purported delegation of authority to allow the Secretary of Health and Human Services ("Secretary") to amend the text of the Act to add vaccines like Gardasil" violates the Presentment Clause of the United States Constitution. U.S. Const. art. I, § 7, cl. 2. Agreeing with this contention (which no court has ever accepted), would result in the effective removal from the Vaccine Act of all of the childhood vaccines developed in the nearly 40 years since its enactment in 1986, notwithstanding decades of vaccine table additions and the routine enforcement of the Act with respect to those "new" vaccines. Indeed, the only authority cited by Plaintiffs in support of this position is the dissenting opinion in *Terran ex rel. Terran v. Secretary of Health and Human*

Services, 195 F.3d 1302, 1312-1314 (Fed. Cir. 1999) (Plager, J. dissenting). The Court declines to so drastically curtail the application of the Vaccine Act.

A. The Vaccine Act and Gardasil's Inclusion in the Vaccine Injury Table

In *Terran*, the authority cited by Plaintiffs, the Court described the purpose, history and overall structure of the Vaccine Act:[1]

> Childhood vaccinations, though an important part of the public health program, are not without risk. Because vaccines often contain either killed bacteria or live but weakened viruses, they can cause serious adverse effects. *See O'Connell v. Shalala*, 79 F.3d 170, 172 (1st Cir. 1996) (citing Committee to Review the Adverse Consequences of Pertussis and Rubella Vaccines, Institute of Medicine, Adverse Effects of Pertussis and Rubella Vaccines 1 (1991)). Despite the relatively rare occurrence of such problems, Congress became concerned that tort liability and related costs might drive up the prices of vaccines and discourage vaccine manufacturers from staying in this market, and that normal tort litigation might leave many sufferers of vaccine-caused injuries uncompensated. *See* H.R.Rep. No. 99–908, at 1, 4, 6–7 (1986), *reprinted in* 1986 U.S.C.C.A.N. 6287, 6344, 6345, 6347–48; *see also O'Connell*, 79 F.3d at 172–73.
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> Accordingly, in 1986, Congress passed the National Childhood Vaccine Injury Act of 1986, Pub.L. No. 99–660, 1986 U.S.C.C.A.N. (100 Stat.) 3755 (codified as amended at 42 U.S.C. §§ 300aa–1 to –34 (1994)), which established a program administered by the Secretary of Health and Human Services ("Secretary") to increase the safety and availability of vaccines. *See* 42 U.S.C. § 300aa–1 (1994). As part of this program, Congress established a Vaccine Injury Compensation Program through which claimants could petition to receive compensation for vaccine-related injuries or death. *See id.* § 300aa–10(a). To receive compensation, a claimant must petition the Court of Federal Claims and demonstrate by a preponderance of the evidence either that (i) the vaccinated child suffered an injury listed on a table, or a complication or "sequela" thereof; or (ii) that the vaccine caused or significantly aggravated the child's injury or condition. *See id.* §§ 300aa–11, –13 to –14; 42 C.F.R. § 100.3 (1996). Thus, the Vaccine Act provides two possible ways for a claimant to receive compensation: first, by showing that she suffered a "table injury," or second, by proving causation in fact. The Vaccine Act establishes an Office of Special Masters within the United States Court of Federal Claims to decide petitions for compensation, provides for review of a Special Master's decision by the Court of Federal Claims, and allows appeal of the Court of Federal Claims' rulings to this court. *See* 42 U.S.C. § 300aa–12 (1994).

[1] This Court has also previously discussed the goals and general operation of the Vaccine Act. *See* Doc. No. 132 at 11-12.

> To aid the Vaccine Program's goal of providing efficient compensation for vaccine injuries, Congress provided, in the form of a table, a list of vaccines, a parallel list of adverse medical conditions commonly associated with the use of each vaccine, and, for certain medical conditions, a time period in which the first symptoms should become apparent following vaccination. *See id.* § 300aa–14(a). These listings comprise the initial Vaccine Injury Table (the "Initial Table"), and are to be read in conjunction with a separate subsection, the "Qualifications and aids to interpretation" (the "QAIs"), that provides explanations and definitions for terms used in the Initial Table. *Id.* § 300aa–14(b). To demonstrate a table injury, a claimant must prove that within the prescribed time period following a vaccination, she suffered one of the disorders set forth on the Vaccine Injury Table corresponding to the vaccine administered. If she cannot make this showing, she must instead prove causation in fact.

Terran, 195 F.3d at 1306–07. Looking beyond the "initial table," which includes only four types of vaccines (DTP; measles, mumps and rubella; polio and inactivated polio), Congress understood that "Additional vaccines" would be developed and enacted a statutory process for their future inclusion. *See* § 300aa–14(a), § 300aa–14(e). The Act provides that when "the Centers for Disease Control and Prevention recommends a vaccine to the Secretary for routine administration to children, the Secretary shall, within 2 years of such recommendation" include the vaccine and related table information in the Vaccine Injury Table. *See* § 300aa–14(e)(2) (for vaccines recommended after August 1, 1993). The Secretary makes these additions to the Table through regulations enacted through the agency's rulemaking authority. *See* § 300aa–14(c)

Also, for the inclusion of a vaccine on the "Table" to actually take effect, Congress needed to extend the excise taxes that supported the initial vaccines to each newly included vaccine. Thus, the 1993 revision to the Act provided that any addition to the Table "by the Secretary under . . . 42 U.S.C. 300aa-14(e)) . . . shall take effect upon the effective date of a tax enacted to provide funds for compensation paid with respect to the vaccine to be added to the vaccine injury table." Pub.L. 103-66, Title XIII, § 13632(a)(3), Aug. 10, 1993, 107 Stat. 646. In other words, vaccines recommended by the CDC can be effectively added to the Table only if Congress, by separate

legislation, enacts a separate excise tax on that vaccine to pay for compensation from the vaccine program.

After the Food and Drug Administration approved Gardasil, the CDC's Advisory Committee on Immunization Practices ("ACIP") voted in 2006 to recommend routine use of HPV vaccines in children. *See* Mortality and Morbidity Weekly Report at 3 (Mar. 23, 2007) (noting approval of the vaccine in June 2006). Also in 2006, Congress expressly added "human papillomavirus vaccines to the list of taxable vaccines" in the Tax Relief and Health Care Act of 2006. Pub. L. 109–432, § 408(b); *see* 26 U.S.C. § 4132(a)(1)(P). The Secretary then added HPV vaccines to the Vaccine Injury Table as of February 1, 2007. *See* 42 C.F.R. § 100.3(c)(7) ("HPV[] vaccines . . . are included on the Table as of February 1, 2007"). Since Gardasil has been included in the Table, courts have recognized it as a vaccine covered by the Vaccine Act. *See, e.g.*, *Cottingham on Behalf of K.C. v. Sec'y of Health & Hum. Servs.*, 971 F.3d 1337, 1340 (Fed. Cir. 2020) ("HPV Vaccines are included on the Vaccine Act's vaccine injury table as of February 1, 2007.").

B. The Presentment Clause and the Vaccine Act

The Presentment Clause of the United States Constitution requires, in relevant part, that "[e]very Bill which shall have passed the House of Representatives and the Senate, shall, before it becomes a Law, be presented to the President of the United States; If he approve he shall sign it, but if not he shall return it," U.S. Const. art. I, § 7, cl. 2. The Constitution thus does not authorize members of the executive branch to enact, amend, or repeal statutes. *See Clinton v. New York*, 524 U.S. 417 (1998) (holding that the Line Item Veto Act violates the Presentment Clause); *INS v. Chadha*, 462 U.S. 919, 954–59 (1983) (striking down a legislative veto provision). Instead, this legislative power is vested exclusively in Congress, and the exercise of such legislative power

must follow the procedures set forth in the Constitution. *See Chadha,* 462 U.S. at 954 ("Amendment and repeal of statutes, no less than enactment, must conform with Art[icle] I."). However, the Presentment Clause is inapplicable to administrative rulemaking in general because rulemaking is by definition not a legislative act, but rather an exercise of executive function properly entrusted to administrative agencies. *See, e.g., American Trucking Assns., Inc. v. United States,* 344 U.S. 298, 310–13 (1953).[2]

In *Clinton* and *Field v. Clark,* 143 U.S. 649 (1892), the Supreme Court discussed the circumstances in which the Presentment Clause bars the exercise of "legislative power" by the Executive branch. In *Field v. Clark,* the Court upheld the constitutionality of the Tariff Act of 1890, Act of Oct. 1, 1890, 26 Stat. 567. That statute contained a list of goods that were exempted from import duties, but a separate provision of the Act directed the President to suspend that exemption for sugar, molasses, coffee, tea, and hides "whenever, and so often" as he should be satisfied that any country producing and exporting those products imposed duties on the agricultural products of the United States that he deemed to be "reciprocally unequal and unreasonable ..." *Id.,* at 612, quoted in *Field,* 143 U.S., at 680; *see Clinton,* 524 U.S. at 442. In rejecting the Presentment Clause challenge, the Supreme Court found that Congress itself made the decision to take the challenged action (imposition of tariffs) based on the occurrence of particular events subsequent to enactment, even though the determination of when and whether such events occurred was up to the President. Specifically, as later emphasized in *Clinton,* 1) the

[2] The scope and exercise of the permissible "delegation" of decision-making authority to federal agencies is not directly at issue here. *See Gundy v. United States*, 588 U.S. 128, 135 (2019) ("a statutory delegation is constitutional as long as Congress 'lay[s] down by legislative act an intelligible principle to which the person or body authorized to [exercise the delegated authority] is directed to conform.'"); *Nat'l Fed'n of Indep. Bus. v. Dep't of Lab., Occupational Safety & Health Admin.,* 595 U.S. 109, 117 (2022) (Administrative agencies are creatures of statute. They accordingly possess only the authority that Congress has provided.)

exercise of the suspension power was contingent upon a condition that did not exist when the Tariff Act was passed; 2) when the President determined that the contingency had arisen, he had a duty to suspend; and 3) whenever the President suspended an exemption under the Tariff Act, he was executing the policy that Congress had embodied in the statute. *See Clinton*, 524 U.S. at 443–44.

In contrast, the Supreme Court in *Clinton* concluded that the Line Item Veto was unconstitutional because it authorized the President himself to effect the repeal of laws, for his own policy reasons, without observing the procedures set out in Article I, § 7. Applying the factors described above, the Supreme Court held that 1) the exercise of the President's cancellation power was based on the same conditions that Congress evaluated when it passed those statutes, not some new occurrence; 2) the President had discretion whether or not to exercise the line item veto; and 3) whenever the President canceled an item of new direct spending or a limited tax benefit he would be rejecting the policy judgment made by Congress and relying on his own policy judgment. *Id*.

The addition of new vaccines to the Vaccine Injury Table satisfies the *Field v. Clark* criteria. In the Vaccine Act, as in the Tariff Act, Congress anticipated that future circumstances might be different (here, new vaccines would be developed) and made plans for that in the Act. Therefore, adding new vaccines is contingent upon a condition that did not exist when the Vaccine Act was first passed. Second, the addition of new vaccines to the Table is not discretionary. The Act requires the Secretary to add all vaccines recommended by the CDC for routine administration to children "within 2 years of such recommendation." *See* § 300aa–14(e)(2). Third, unlike in *Clinton*, the Secretary is plainly following, rather than contravening, Congress's policy under the Vaccine Act by adding newly developed vaccines to the Table. Moreover, as discussed below, because additions of newly developed vaccines must effectively be ratified by Congress through

tax legislation, the scope of Congress's "delegation" is further limited. Therefore, the Secretary's inclusion of "Additional vaccines" in accordance with the specific directions in the statute does not violate the Presentment Clause of the Constitution.

As noted, Plaintiffs' position has never been accepted by any court. Further, even putting aside that it is a 25-year old case cited only for its dissent, Plaintiffs' reliance on *Terran* is misplaced. In *Terran*, the plaintiff argued that changes that had been made by the Secretary to the compensable table injuries for DTP, one of the initial table vaccines, were unconstitutional. Whatever the constitutionality of changes to an existing portion of the Act might be (and the Court does not express any view as to that issue except to note that it has never been contradicted by the Federal Circuit or any other), that does not address the issue here, which is the addition to the Table of vaccines that did not exist when the statute was enacted (but which were specifically contemplated by the 1993 amendments to the Act). Indeed, even the *Terran* dissent suggests that situation might be different.[3] *Terran*, 195 F.3d at 1321. ("If Congress in the Vaccine Act had specified certain external events upon the happening of which the enacted table became no longer effective, and at which time the Secretary was to create a revised injury table, and left to the Secretary the determination of when the specified events in fact occurred, the analysis *might* be different."). Accordingly, the Court does not find Plaintiffs' cited authority persuasive.

Finally, even if the Presentment Clause was applicable to the addition of new vaccines to the Vaccine Injury Table, the inclusion of HPV vaccines (including Gardasil) in the Vaccine Act program has been favorably voted on by Congress and signed by the President. As discussed above, for a vaccine to become an effective part of the Vaccine Act, an excise tax on that vaccine

[3] The *Terran* dissent also notes that Congress could properly direct the Secretary to create/revise a Vaccine Injury Table through administrative rulemaking authority, which is indeed the process by which new vaccines are added to the Table. *See Terran*, 195 F.3d at 1321

must be approved by Congress and the President to fund the compensation required by the Act. This was done in the Tax Relief and Health Care Act of 2006 when Congress expressly added "human papillomavirus vaccines to the list of taxable vaccines." Pub. L. 109–432, § 408(b). The only reason to create this excise tax was to further the vaccine's effective inclusion in the Table as part of the Vaccine Act program. Accordingly, the constitutional separation of powers has been fully satisfied with respect to Gardasil's inclusion into the Vaccine Act.

C. Other Issues

Merck has raised other issues – judicial estoppel, administrative exhaustion and waiver – that the Court need not and does not reach. However, as discussed above, the Court finds that even though the Court did not have generally applicable constitutional arguments in mind when it granted leave for other plaintiffs to raise individual circumstances that might lead to a different result on the issues presented in the Motion for Judgment on the Pleadings, it is most efficient and in the broader interest of the MDL that the Court resolve Plaintiffs' constitutional challenge on the merits in this Order.

III. ORDER

NOW THEREFORE IT IS ORDERED THAT:

1. Plaintiffs' Motion to Limit Application of the Court's Order on Defendant's Motion for Partial Judgment on the Pleadings to Plaintiffs Bergin and America and Motion to Find that Subjecting Gardasil Personal Injury Claims to the Vaccine Act Violates the Presentment Clause of the United States Constitution, (Doc. No. 136), are **DENIED;** and

2. This matter case shall proceed in the course set by the Court's operative case management orders in the absence of a voluntary resolution of the dispute among the parties.

SO ORDERED ADJUDGED AND DECREED.

Signed: June 27, 2024

Kenneth D. Bell
United States District Judge